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| APPLICATION NO. | FI | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|------------|-------------|----------------------|---------------------|------------------|
| 10/510,716 | 10/18/2004 | | Yoshihiro Hakamada | 260068US0PCT 2844 | |
| 22850 | 7590 | 06/30/2006 | | EXAMINER | |
| OBLON, S. 1940 DUKE | • | MCCLELLAND, | raghu, ganapathiram | | |
| ALEXANDRIA, VA 22314 | | | | ART UNIT | PAPER NUMBER |
| | , | | | 1652 | |

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | | |
|--|--|--|--|--|--|--|--|
| | 10/510,716 | HAKAMADA ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Ganapathirama Raghu | 1652 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirn rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE! | J. lely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on 18 O | <u>ctober 2004</u> . | | | | | | |
| 24) | | | | | | | |
| · · · · · · · · · · · · · · · · · · · | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims | | | | | | | |
| 4) Claim(s) <u>1-9</u> is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6) Claim(s) 1-9 is/are rejected. | | | | | | | |
| 7) Claim(s) is/are objected to. | r election requirement. | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Application Papers | | | | | | | |
| 9) ☐ The specification is objected to by the Examine | | | | | | | |
| 10) \boxtimes The drawing(s) filed on <u>18 October 2004</u> is/are: a) \boxtimes accepted or b) \square objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of: | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | | | | | | | |
| Attachment(s) | _ | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summary Paper No(s)/Mail D | | | | | | |
| Notice of Draftsperson's Patent Drawing Review (₹10-946) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/8/04, 08/09/05. | | Patent Application (PTO-152) | | | | | |

Claims 1-9 are pending in this application and are now under consideration for

examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35

U.S.C. 119(a)-(d). This application is a 371 of PCT/JP03/05371 and claims the priority

date of Japanese application 2002-124474 filed on 04/25/2002. However, examiner

notes that the English translation for the Japanese application 2002-124474 is not

provided.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 18 Oct. 2004 and 09

Aug. 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the

Examiner is considering the information disclosure statement.

Drawings

The drawings are considered for examination purposes only.

Specification

The disclosure is objected to because of the following informalities: Spelling and

grammar errors are noted in the specification. For example, Page 2, paragraph 2 recites

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the phrase "meanshile...", should read as "meanwhile...". Appropriate correction is

required.

Claim Rejections 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and

requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claim could read on a non-

statutory subject matter. The claim is drawn to "A transformant...", which could be a

human being. Claim directed to such matter are considered non-statutory. Examiner

suggests amending the claim to recite "An isolated transformed host cell" to show the

hand of man and in order to overcome the rejection. Appropriate correction is required.

Claim Rejections 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specifi cation shall conclude with one or more claims particularly pointing out and distinctly claiming the

subject matter which the applicant regards as his invention.

Claim 1 and claims 2-9 depending therefrom are rejected under 35 U.S.C. 112,

second paragraph, as being indefinite for failing to particularly point out and distinctly

claim the subject matter which applicant regards as the invention. Claim 1 recites the

phrase "...an amino acid sequence represented by SEQ ID NO: 2 ...". It is not clear to

the examiner whether as to what this phrase means in the context of the above claim. It

is not clear whether the isolated amino acid indeed actually has the sequence SEQ ID

NO: 2 or whether SEQ ID NO: 2 is a representative sequence of the isolated

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pol ypeptide. Examiner suggests applicants to make a direct reference to the SEQ ID

NO: 2 such as "the amino acid sequence of SEQ ID NO: 2 ...".

Claim 1 and claims 2-9 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-3 recites the phrase "...or from corresponding positions ...". It is not clear to the examiner what this phrase means in the context of the above claim, "corresponding positions" of what? Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 and claims 4-9 depending therefrom are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to a mutated alkaline cellulase obtained by deleting, from a cellulase having an amino acid sequence represented by SEQ ID NO: 2 or an amino acid sequence exhibiting 90% homology to SEQ ID NO: 2, one or more amino acid residues chosen from positions 343-377 and inserting 2-15 amino acids into at least one deleted position such that claim 1 includes alkaline cellulases containing an insertion from 2-375

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unspecified amino acids as replacement for 1-25 amino acids of SEQ ID NO: 2 or a enzyme homologous thereto. Claims 4-5 are directed to said mutated alkaline cellulase, wherein the peptide to be inserted contains as structural amino residues alanine and glycine or alanine and histidine or alanine and arginine (claim 4) and the peptide to be inserted is alanine-glycine-alanine or alanine-histidine-alanine or alanine-arginine-alanine (claim 5). Claims 6-9 are directed to gene encoding said mutated polypeptide, vector and an isolated host cell. Claims 1 and 4-9 are rejected under this section 35 U.S.C. 112, because the claims are directed to a genus of polypeptides, i.e., mutated alkaline cellulase obtained by deleting, from a cellulase having an amino acid sequence represented by SEO ID NO: 2 or an amino acid sequence exhibiting 90% homology to SEQ ID NO: 2, one or more amino acid residues chosen from positions 343-377 and inserting 2-15 amino acids into at least one deleted position such that claim 1 includes alkaline cellulases containing an insertion from 2-375 unspecified amino acids as replacement for 1-25 amino acids of SEQ ID NO: 2 or a enzyme homologous thereto, with no support in the specification for the structural details of all species of genus associated with the function i.e., alkaline cellulase activity., vector and host cell has been provided in the specification for the claims. The specification discloses the isolation of a polypeptide from Bacillus sp., KSM-S237, a cellulase with SEQ ID NO: 2 (Egl-237) and three mutants with alkaline cellulase activity by deleting the amino acid residues spanning the region of 357-362 of SEQ ID NO: 2 and inserting alanine-glycine-alanine or alanine-histidine-alanine or alanine-arginine-alanine (Example 1, page 13 of Specification), the disclosed species which replace a short peptide region with three specific other short peptides i.e., alanineglycine-alanine or alanine-histidine-alanine or alanine-arginine-alanine would not be

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representative of scope of modification encompassed in claim 1, such that claim 1 includes alkaline cellulases containing an insertion from 2-375 unspecified amino acids as replacement for 1-25 amino acids of SEQ ID NO: 2 or a enzyme homologous thereto. No information, beyond the characterization of the polypeptide, a cellulase with SEQ ID NO: 2 (Egl-237) and three mutants with alkaline cellulase activity by deleting the amino acid residues spanning the region of 357-362 of SEQ ID NO: 2 and inserting alanineglycine-alanine or alanine-histidine-alanine or alanine-arginine-alanine has been provided by the applicants, which would indicate that they had possession of claimed mutated alkaline cellulase obtained by deleting, from a cellulase having an amino acid sequence represented by SEQ ID NO: 2 or an amino acid sequence exhibiting 90% homology to SEO ID NO: 2, one or more amino acid residues chosen from positions 343-377 and inserting 2-15 amino acids into at least one deleted position such that claim 1 includes alkaline cellulases containing an insertion from 2-375 unspecified amino acids as replacement for 1-25 amino acids of SEQ ID NO: 2 or a enzyme homologous thereto. The specification does not contain any disclosure of the sequence and structure of all the polypeptides within the scope of the claimed genus. The disclosed information is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus of polypeptides. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

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Claim 1 and claims 2, 4-9 depending therefrom are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide from Bacillus sp., KSM-S237, a cellulase with SEQ ID NO: 2 (Egl-237) and three mutants with alkaline cellulase activity by deleting the amino acid residues spanning the region of 357-362 of SEO ID NO: 2, and inserting alanine-glycine-alanine or alanine-histidinealanine or alanine-arginine-alanine, expression vector and isolated host cell, does not reasonably provide enablement for any isolated mutated alkaline cellulase from any source obtained from a cellulase having an amino acid sequence represented by SEQ ID NO: 2 or an amino acid sequence exhibiting 90% homology to SEQ ID NO: 2, furthermore in said sequence one or more amino acid residues chosen from positions 343-377 is deleted and inserting 2-15 amino acids into at least one deleted position or in said sequence one or more amino acid residues chosen from positions 357-362 is deleted and inserting 2-5 amino acids into at least one deleted position or in said sequence all of the amino acid residues chosen from positions 357-362 is deleted and inserting 2-5 amino acids into the deleted position, gene encoding mutated polypeptides, vector and host cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with the claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the

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nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-2 and 4-9 are so broad as to encompass any mutated alkaline cellulase from any source obtained from a cellulase having an amino acid sequence represented by SEO ID NO: 2 or an amino acid sequence exhibiting 90% homology to SEQ ID NO: 2, furthermore in said sequence one or more amino acid residues chosen from positions 343-377 is deleted and inserting 2-15 amino acids into at least one deleted position or in said sequence one or more amino acid residues chosen from positions 357-362 is deleted and inserting 2-5 amino acids into at least one deleted position or in said sequence all of the amino acid residues chosen from positions 357-362 is deleted and inserting 2-5 amino acids into the deleted position, gene encoding mutated polypeptides, vector and host cell. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides and encoding polypeptides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires knowledge and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to an isolated polypeptide from Bacillus sp., KSM-S237, a cellulase with SEQ ID NO: 2 (Egl-237) and three mutants with alkaline cellulase activity by deleting the amino acid

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residues spanning the region of 357-362 of SEO ID NO: 2, and inserting alanine-glycinealanine or alanine-histidine-alanine or alanine-arginine-alanine, does not reasonably provide enablement for any mutated alkaline cellulase from any source obtained by deleting, from a cellulase having an amino acid sequence represented by SEQ ID NO: 2 or a amino acid sequence exhibiting 90% homology to SEQ ID NO: 2, furthermore in said sequence one or more amino acid residues chosen from positions 343-377 is deleted and inserting 2-15 amino acids into at least one deleted position or in said sequence one or more amino acid residues chosen from positions 357-362 is deleted and inserting 2-5 amino acids into at least one deleted position or in said sequence all of the amino acid residues chosen from positions 357-362 is deleted and inserting 2-5 amino acids into at least one deleted position. It would require undue experimentation of the skilled artisan to make and use the claimed polypeptides and encoding polynucleotides. The specification is limited to teaching the use of a cellulase, an isolated polypeptide from Bacillus sp., KSM-S237, a cellulase with SEQ ID NO: 2 (Egl-237) and three mutants with alkaline cellulase activity by deleting the amino acid residues spanning the region of 357-362 of SEQ ID NO: 2, and inserting alanine-glycine-alanine or alanine-histidine-alanine or alanine-arginine-alanine, but provides no guidance with regard to the making of other variants and mutants from any source or with regard to other uses. In view of the great breadth of the claims, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require

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undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by these claims.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions or deletions.

The specification does not support the broad scope of the claims which encompass all modifications of an isolated polypeptide encoding an alkaline cellulase from any source, wherein said polypeptide is a mutated alkaline cellulase obtained by deleting, from a cellulase having an amino acid sequence represented by SEQ ID NO: 2 or an amino acid sequence exhibiting 90% homology to SEQ ID NO: 2, furthermore in said sequence one or more amino acid residues chosen from positions 343-377 is deleted and inserting 2-15 amino acids into at least one deleted position or in said sequence one or more amino acid residues chosen from positions 357-362 is deleted and inserting 2-5 amino acids into at least one deleted position or in said sequence all of the amino acid residues chosen from positions 357-362 is deleted and inserting 2-5 amino acids into the deleted position, expression vector and host cell, because the specification does not establish: (A) regions of an alkaline cellulase having replacements of all or a portion of a 25 residue long fragment with anything from 2-375 unspecified amino acids in the

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protein/polynucleotide structure without affecting the activity of the encoded cellulase; (B) the general tolerance of the polypeptide and the polynucleotide encoding cellulase to said modification and extent of such tolerance; (C) a rational and predictable scheme for said modification with any amino acid residue or the respective codon in the polynucleotide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polypeptides with an enormous number of modifications. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because, while claim 8 is enabling for an isolated host cell transformed with the synthetic nucleic acid i.e., an isolated nucleic acid molecule from *Bacillus sp.*, KSM-S237 encoding a cellulase comprising SEQ ID NO: 2 (Egl-237) and three mutants with alkaline cellulase activity by deleting the amino acid residues spanning the region of 357-362 of SEQ ID NO: 2, and inserting alanine-glycine-alanine

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or alanine-histidine-alanine or alanine-arginine-alanine, expression vector and isolated host cell, does not reasonably provide enablement for transgenic multi-cellular organisms or host cells within a multi-cellular organism that have been transformed with said synthetic nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 8 is so broad as to encompass host cells transformed with specific nucleic acids, including cells in in vitro culture as well as within any multi-cellular organism. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to extremely large number of transformed host cells broadly encompassed by the claim. While methods for transforming cells in vitro are well known in the art, methods for successfully transforming cells within complex multicellular organisms are not routine and are highly unpredictable. Furthermore, methods for producing a successfully transformed cell within the multi-cellular organism are unlikely to be applicable to transformation of other types of multi-cellular organism as multi-cellular organisms vary widely. However, in this case the disclosure is limited to only isolated host cells in vitro. Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the use of host cells within a multi-cellular organism for the production of polypeptide. The scope of claim must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA)). Without sufficient guidance, expression of genes in a particular host cell and having the desired biological characteristics is unpredictable, the

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experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F. 2d 731, 8 USPQ 2nd 1400 (Fed. Cir., 1988). It is suggested that the applicants limit the claims to "An isolated host cell ...".

Claim Rejections 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sumitomo et al., (Biosci. Biotech. Biochem., 1992 Vol. 56 (6): 872-877). Claim 1 is directed to a mutated alkaline cellulase obtained from a cellulase having an amino acid sequence represented by SEQ ID NO: 2 or an amino acid sequence exhibiting 90% homology to SEQ ID NO: 2, furthermore in said sequence one or more amino acid residues chosen from positions 343-377 is deleted and inserting 2-15 amino acids into at least one deleted position. Claims 6-9 are directed to a gene encoding said polypeptide, expression vector and an isolated host cell comprising said vector. Sumitomo et al., (*supra*) have disclosed a gene for an alkaline endoglucanase from alkalophilic *Bacillus sp.*, KSM-64 that has 92.3 % homology to SEQ ID NO: 2 of the instant application with mutations in positions 363, 370 and 373 of SEQ ID NO: 2 and having alkaline β 1-4 endoglucanase activity (Abstract section, page 872; see sequence alignment provided).

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supported by the instant application in the specification (Background art, third paragraph, page 1; alkaline cellulase derived from Bacillus sp. KSM-64 Sumitomo et al., Biosci. Biotech. Biochem., 1992 Vol. 56 (6): 872-877). Examiner takes the position that the polypeptide disclosed by Sumitomo et al., is a variant of SEQ ID NO: 2 or a protein 90% identical thereto and comprising changes in one or more amino acid residues chosen from the 343-377 position in SEQ ID NO: 2 of the instant application. Said reference also discloses expression vector, host cells and the method of making said polypeptide. Therefore, the reference of Sumitomo et al., anticipates claims 1 and 6-9 of the present invention as written.

Claims 1 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Endo et al., of KAO Corp., (JP20012315669, publication date 08/28/2001, see English translation provided; see sequence alignment provided). Claim 1 is directed to a mutated alkaline cellulase obtained by deleting, from a cellulase having an amino acid sequence represented by SEQ ID NO: 2 or an amino acid sequence exhibiting 90% homology to SEQ ID NO: 2, furthermore in said sequence one or more amino acid residues chosen from positions 343-377 is deleted and inserting 2-15 amino acids into at least one deleted position. Claims 6-9 are directed to a gene encoding said polypeptide, expression vector and an isolated host cell comprising said vector. Endo et al., of KAO Corp., (*supra*) have disclosed a gene for an alkaline cellulase from *Bacillus sp.*, that has 94.6 % homology to SEQ ID NO: 2 of the instant application with mutations in positions 363, 370 and 373 of SEQ ID NO: 2 and having alkaline cellulase activity (Abstract section, page 872; see sequence alignment provided). β 1-4 endoglucanases are a family of enzymes generally

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referred to as celluases and supported by the instant application in the specification (Background art, third paragraph, page 1; alkaline cellulase derived from Bacillus sp. KSM-64 Sumitomo et al., Biosci. Biotech. Biochem., 1992 Vol. 56 (6): 872-877). Examiner takes the position that the polypeptide disclosed by Endo et al., of KAO Corp., is a variant of SEQ ID NO: 2 or a protein 90% identical thereto and comprising changes in one or more amino acid residues chosen from the 343-377 position in SEQ ID NO: 2 of the instant application. Said reference also discloses expression vector, host cells and the method of making said polypeptide. Therefore, the reference of Endo et al., of KAO Corp., anticipates claims 1 and 6-9 of the present invention as written.

Examiner has given the priority date of 04/25/2003 for the instant application as no English translation is provided for the foreign priority claimed to Japanese application 2002-124474 filed on 04/25/2002.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D. Patent Examiner Art Unit 1652

June 12, 2006.

REBECCA E. PROUTY PRIMARY EXAMINER GROUP 1800